DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	2/9/2026-2/13/2026
	FEI NUMBER 3006404071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven C. Melchiode, President

FIRM NAME	STREET ADDRESS
SpineSmith Holdings, LLC	4719 S Congress Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78745-2302	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

In product realization planning your firm did not adequately determine, as appropriate, quality objectives and requirements for the product, required activities specific to the product together with criteria for product acceptance and records needed to provide evidence that the realization processes and resulting product meet requirements.

Specifically, your firm has failed to adequately define quality objectives and requirements for your Class II medical device system, intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis, to ensure the realization processes and resulting product meets requirements.

During a review of your firm's recommended procedural guidelines for the (b) (4) (b) (4), it was observed that temperature, duration and attachment requirements have been defined for specified treatment areas. However, these requirements have not been defined within (b) (4) (b) (4), Rev. E, effective 03/21/2018 or included as acceptance criteria within the functional verification tests, (b) (4), Rev. B, effective 3/13/2017, and (b) (4), Rev. A, effective 9/19/2017. Furthermore, due to your firm's inadequate definition of quality objectives and requirements for the product, the product specification provided to the contract manufacturer and batch records received from

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Katherine M Thames, Investigator	X Katherine M Thames Investigator Signed By: KATHERINE M. THAMES -S Date Signed: 02-13-2026 10:28:02	2/13/2026

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the contract manufacturer, for the medical device and attachments, do not contain the evidence that the realization processes and resulting product meets requirements.

Additionally, your firm's Risk Report Form, Risk ID# RA-2025-16, effective 8/29/2025, defines failure modes within the device's design, manufacturing process, and use which could result in injury to the patient or user. Since 2023, your firm has received over 25 complaints for heating-related errors or failures.

OBSERVATION 2

The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not adequately established and implemented.

Specifically, your firm failed to establish and implement the activities necessary to ensure that your Class II medical device system, intended for use in (b) (4) and (b) (4) for (b) (4) and (b) (4), and your Class II medical device, intended for processing bone marrow aspirate, meet the specified purchasing requirements.

Your firm's Product Testing & Inspection & Release Procedure, QS-114, Rev. 6, effective 03/17/2025, defines that personnel will complete inspections to ensure final testing packages include documentation of any applicable product-specific testing and inspection forms. However, during a review of device batch records, it was observed that product-specific testing, regarding the sterility and electrical performance requirements, was not adequately reviewed or collected from the applicable contract manufacturer.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."